

Claims

What is claimed is:

1. A container for packaging azithromycin made of gas impermeable material
5 wherein after storage azithromycin degradation products do not exceed 5% by weight of the azithromycin.
2. The container according to claim 1, wherein after storage azithromycin degradation products do not exceed 3% by weight of azithromycin.
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3. The container according to claim 1, wherein the gas impermeable material is laminated aluminum.
4. The container according to claim 1 or 3, wherein the container comprises
15 at least one additional layer of aluminum.
5. The container according to claim 1 or 2, wherein the azithromycin is azithromycin solvate.
- 20 6. The container according to claim 5, wherein the azithromycin is selected from the group consisting of ethanol solvate, propanol solvate, and a hydrate.
7. The container according to claim 6, wherein the azithromycin is monohydrate azithromycin.
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8. A container for packaging azithromycin monohydrate made of gas impermeable material wherein after storage less than about 5% of azithromycin monohydrate is transformed to azithromycin dihydrate upon storage of one year.
- 30 9. The container according to claim 8, wherein the gas impermeable material is laminated aluminum.
10. The container according to claim 1, wherein the container is made of a bag or pouch.

11. The container according to claim 1, wherein the gas impermeable material is impermeable to oxygen.

5 12. The container according to any one of claims 1 and 2, wherein the gas impermeable is on the interior of the package.

13. The container according to any one of claims 1 and 2, wherein the azithromycin is stored at a temperature of about 25°C to about 55°C.

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14. The container according to any one of claims 1 and 2, wherein the azithromycin is stored at 60% relative humidity.

15 15. The container according to any one of claims 1 and 2, wherein the azithromycin is stored for at least one month.

16. The container according to any one of claims 1 and 2, wherein the degradation products are identified by HPLC relative to retention times of about 0.26, 0.34, 0.37, or 0.80.

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17. A method for storing azithromycin comprising packaging azithromycin in a container comprising a gas impermeable material wherein after storage azithromycin degradation products do not exceed 5% by weight of the azithromycin.

25 18. The method according to claim 17, wherein the gas impermeable material is laminated aluminum.

19. The method according to claim 18, wherein the container further comprises at least one additional later of laminated aluminum.